Original Article

CLINICAL REHABILITATION

Clinical Rehabilitation
1–13

DOI: 10.1177/0269215521995671
journals.sagepub.com/home/cre
SAGE

Supporting wellbeing through peer-befriending (SUPERB) for people with aphasia: A feasibility randomised controlled trial

Katerina Hilari[1], Nicholas Behn[1*], Kirsty James[2], Sarah Northcott[1], Jane Marshall[1], Shirley Thomas[3], Alan Simpson[4], Becky Moss[1], Chris Flood[5], Sally McVicker[1] and Kimberley Goldsmith[2]

Abstract

Objective: To determine the feasibility and acceptability of peer-befriending, for people with aphasia.

Design: Single-blind, parallel-group feasibility randomised controlled trial comparing usual care to usual care + peer-befriending.

Participants and setting: People with aphasia post-stroke and low levels of distress, recruited from 5 NHS Hospitals and linked community services; their significant others; and 10 befrienders recruited from community.

Intervention: Six 1-hour peer-befriending visits over three months.

Main measures: Feasibility parameters included proportion eligible of those screened; proportion consented; missing data; consent and attrition rates. Acceptability was explored through qualitative interviews. Outcomes for participants and significant others were measured at baseline, 4- and 10-months; for peer-befrienders before training and after one/two cycles of befriending.

Results: Of 738 patients identified, 75 were eligible of 89 fully screened (84%), 62 consented (83% of eligible) and 56 randomised. Attrition was 16%. Adherence was high (93% attended ⩾2 sessions, 81% all six). The difference at 10 months on the GHQ-12 was 1.23 points on average lower/better in the intervention arm (95% CI 0.17, −2.63). There was an 88% decrease in the odds of GHQ-12 caseness (95% CI 0.01, 1.01). Fourty-eight significant others and 10 peer-befrienders took part. Procedures and outcome measures were acceptable. Serious adverse events were few ($n = 10$, none for significant others and peer-befrienders) and unrelated.

[1]Centre for Language and Communication Science Research, City, University of London, London, UK
[2]King's Clinical Trials Unit, King's College London, London, UK
[3]University of Nottingham, Nottingham, UK
[4]Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care, King's College London, London, UK
[5]School of Health and Social Care, London South Bank University, London, UK

*Joint first authors

Corresponding author:
Katerina Hilari, Centre for Language and Communication Science Research, City, University of London, Northampton Square, London EC1V0HB, UK.
Email: k.hilari@city.ac.uk
Twitter: @CityLCS; @Katerina Hilari

Conclusions: SUPERB peer-befriending for people with aphasia post-stroke experiencing low levels of distress was feasible. There was preliminary evidence of benefit in terms of depression. Peer-befriending is a suitable intervention to explore further in a definitive trial.
Clinical trial registration-URL: http://www.clinicaltrials.gov Unique identifier: NCT02947776
Subject terms: Translational research, mental health, rehabilitation, quality and outcomes, stroke

Keywords
Feasibility study, peer-befriending, aphasia, mood

Received: 9 November 2020; accepted: 28 January 2021

Introduction

The communication disability of aphasia affects about a third of the acute stroke population and 16%–30% in the long-term.[1] The psychological needs of people with aphasia seem greater than in general stroke, with a reported 62% rate of depression one year post-stroke.[2] Depression post-stroke is associated with worse rehabilitation outcomes, increased carer strain, increased healthcare utilisation and higher mortality.[3–5] Despite the greater needs of people with aphasia, they are often excluded from mental health interventions due to their communication difficulties[6] and from trials on the effectiveness of psychological therapies for post-stroke depression.[7] There is pressing need to systematically evaluate interventions to improve wellbeing for people with aphasia.

Interventions for people with aphasia with no/mild mood problems that avert some of the long-term psychological consequences of stroke may prevent the need for more complex and costly psychological therapies. In this study we explored one such intervention, peer-befriending. Compared to group peer-support, which is common after stroke, one-to-one peer-befriending may be more suitable for those with limited mobility and/or aphasia and reduced capacity or confidence to get out of the house. Peer-befriending in stroke has only been evaluated within a hospital setting and excluded people with severe aphasia.[8] Peer-befrienders can offer empathy, support, companionship, hope and share experiences and ideas about how to cope.[9] In a meta-analysis of befriending across different populations, significant positive effects were reported on depressive symptoms (standardised mean difference −0.27, 95% CI −0.48, −0.06).[10]

This is the first trial of peer-befriending for people with aphasia. We explored the feasibility of peer-befriending for people with aphasia and low levels of distress, recruited at a time of increased need - when they are discharged from hospital and active care is withdrawn.[11] Given that peer-befriending has the potential to impact not just people with aphasia receiving it, but also their significant others and the peer-befrienders themselves, we considered all three of these groups in our study. Specifically, SUPERB addressed the following objectives:

1. Explore the feasibility of a phase-III RCT based on (a) feasibility of recruitment and retention, (b) acceptability of research procedures and outcome measures, (c) acceptability of usual care + peer-befriending (Peer) versus usual care control (Usual), (d) documentation of usual care and (e) treatment fidelity of peer-befriending.
2. Explore psychological and social wellbeing outcomes as outcomes in a definitive trial for (a) people with aphasia receiving Peer versus Usual, (b) their significant others and (c) peer-befrienders.
3. Explore the feasibility of a full economic evaluation of Peer versus Usual.

Here we report on the main feasibility outcomes of the trial, that is, feasibility of recruitment and retention, acceptability of research procedures and outcome measures and clinical outcomes. SUPERB included a nested qualitative study (1b–c), an exploration of treatment fidelity (1e) and a health economic evaluation (1d, 3) not reported here; only

data on the acceptability of study procedures and outcome measures (1b) from the qualitative study are included.

Methods

SUPERB was a single-blind parallel-group feasibility trial with follow-up assessments at 4- and 10-months post-randomisation. Participants were recruited April 2017–October 2018. Ten-month follow-up was completed in August 2019. The trial was registered at clinicaltrials.gov (NCT02947776). The trial protocol was published in January 2019[12] with detailed description of the trial methods; a summary is provided here. Ethical approval was granted by the London Bloomsbury National Health Service ethics committee (ref 16/LO/2187). SUPERB was funded by The Stroke Association. City, University of London was the research sponsor. Reporting follows the CONSORT 2010 Statement: extension to randomised pilot and feasibility trials.

We recruited participants from hospitals within North London boroughs, linked community services and GP practices. Participants provided informed written consent. Baseline assessments were completed when people with aphasia were discharged from hospital to the community and where applicable had completed intensive rehabilitation (early supported discharge). Due to this time interval between screening and involvement in the study for those recruited from hospitals, participants received a second screen in the community if they had expressed an interest in the study but had not met, while in hospital, specific eligibility criteria that could change (e.g. borderline cut-off for low distress; vision and hearing problems that could be corrected).

Participants were eligible if they were: >18 years old; pre-morbidly fluent in English; diagnosed with aphasia due to stroke; experiencing low levels of distress (based on Depression Intensity Scale Circles (DISCS)[13] cut-offs). Those experiencing higher levels of distress, either received or were referred on for more appropriate psychological support. Exclusion criteria comprised: diagnosed with conditions effecting cognition or mental health; experiencing severe uncorrected visual or hearing problems; diagnosed with severe or potentially terminal co-morbidities; and discharged outside of the borough of the recruiting hospital. Participants nominated a significant other, their closest confidant, to take part but this did not affect eligibility of the participant. Peer-befrienders were people with mild-moderate aphasia and ⩾1-year post-stroke, nominated by community services and screened by the trial manager. The same exclusion criteria applied to significant others and peer-befrienders, bar discharge destination. All peer-befrienders and a purposive sample of participants ($n = 20$, 10 from each arm) and significant others ($n = 10$, 5 from each arm) also took part in qualitative interviews.

Randomisation of participants in a 1:1 Peer to Usual ratio via an independent randomisation service at King's Clinical Trials Unit utilising minimisation with a random component occurred following baseline assessments. Minimisation stratifiers were: severity of aphasia (Western Aphasia Battery-Revised (WAB-R)[14] cut-offs), recruitment area (Hackney, Tower Hamlets, Camden & Islington) and physical mobility (wheelchair-user or not).

To minimise participant unblinding, a two-stage consent process was followed.[12] All participants consented to a study on adjustment post-stroke; with comparison of different packages of care without specifics regarding the intervention. Those randomised to Peer were then provided with full intervention details and further consent sought. The trial statisticians remained partially blind (only aware of coded trial arm) until the main analysis code was written and reviewed. Outcome assessors were blind to treatment allocation.

All participants received usual care, that is, all health and social care and voluntary services available within their boroughs. This was documented using the Client Service Receipt Inventory[15] and is reported elsewhere.

Participants in Peer were visited by trained, regularly supervised peer-befrienders in their homes six times over three months (sessions lasting approximately one hour). Two optional sessions were offered at the end of this period to aid transition to the end of peer-befriending. Pairings took account of preferences around interests, cultural factors, gender and age. In the first meeting possible

goals and the schedule of visits was discussed. Subsequent visits included conversation, problem-solving, trips out, for example, to a local group and joint activities. Full details of the intervention, including peer-befriender training, are in the protocol TIDieR checklist.[12]

Feasibility outcomes comprised: proportion eligible of those screened; proportion who consent of those eligible; rate of eligibility, consent and recruitment (participants randomised) per month; frequency and proportion of people consented who withdraw (overall, by study group, before/after randomisation and specifically those in Peer who decline consent at the second stage). Acceptability of study procedures and outcome measures was based on completion rates, adverse events and qualitative interviews.

At baseline, 4- and 10-months post-randomisation, outcomes for likely use in a definitive trial were measured face-to-face with participants with aphasia and befrienders and face-to-face, over the phone or by email/post from significant others. To ensure participants with aphasia would be able to complete the measures used, assessors were experienced in communicating with people with aphasia, they were trained on the outcome measures and they used assessment packs with scripted instructions. Moreover, with the exception of the wellbeing measure below, we used measures that have been either validated with people with aphasia or successfully used with them in previous research studies. Lastly, the presentation of measures was modified to make them more aphasia friendly (e.g. key words in bold, few items per page).

Participants with aphasia completed:

- General Health Questionnaire-12 (GHQ-12),[16] using 0–0–1–1 scoring (primary outcome).
- DISCS (primary outcome if there is $\geqslant 10\%$ missing data in the GHQ-12 due to aphasia severity).
- Proportion with high (score $\geqslant 3$) versus low distress (score 0–2) on GHQ-12.
- Short Warwick Edinburgh Mental Wellbeing Scale-7.[17]
- Communication Participation Item Bank.[18]
- Community Integration Questionnaire – Adapted.[19]
- Communication Confidence Rating Scale for people with Aphasia.[20]
- Friendship Scale.[21]

At the same timepoints significant others completed the Warwick Edinburgh Mental Wellbeing Scale,[22] GHQ-28[16] with 0–0–1–1 scoring and the Bakas Caregiving Outcome Scale).[23] Outcomes for peer-befrienders were collected at baseline and on completion of two befriending cycles (one, if completing only one): Warwick Edinburgh Mental Wellbeing Scale, Community Integration Questionnaire – Adapted, General Self-Efficacy Scale.[24] The GHQ-12 was also completed by peer-befrienders as a safety measure to monitor distress.

We planned to recruit 60 participants with aphasia (30 per arm). This sample size was adequate to estimate parameters to inform the design and sample size of a full trial and met recommendations for feasibility studies.[25] We recruited 62 and randomised 56 participants. We planned to recruit and recruited 10 peer-befrienders.

In terms of data analysis, feasibility outcomes were estimated as frequencies and proportions (with associated binomial exact 95% confidence intervals [CI]) or rates (with Poisson 95% CI) as appropriate using the CONSORT diagram. Potential future trial outcomes were summarised overall and by arm and time point using means and standard deviations (SDs) or medians and interquartile ranges (IQRs) as appropriate.

The differences in mean outcomes between those randomised to Peer and Usual by intention to treat at 4- and 10-months post randomisation and associated 95% CI were estimated using linear mixed models with maximum likelihood estimation and a random effect for participant. Dependent variables were post-treatment measures of the outcome at 4 and 10 months. Fixed effects comprised baseline measures of the outcome; trial arm; randomisation stratifiers (mobility, severity, site; and a dummy variable for time); a trial arm x time interaction term; and education and ethnicity, which were potentially unbalanced at baseline (decided posthoc). No formal significance tests were carried out. Effect sizes were calculated by dividing the mean differences by respective baseline SDs over

the whole sample, to enable comparisons across measures and time points in baseline SD units.

The arms were compared on dichotomised GHQ-12 caseness (high distress = score ⩾3, low distress = score 0–2) using odds ratios estimated from mixed effects logistic regression with the same fixed effects and random intercept as for the linear regression.

The GHQ-12 intra-class correlation coefficient (ICC) was also calculated to investigate the clustering of participants in the intervention arm who were seen by the same peer-befriender using a linear mixed effects model with the 4- and 10-months post-randomisation measures as dependent variables and a random intercept for befriender.

A per protocol analysis was also carried out removing seven participants from the PEER arm who declined consent at the second stage or attended fewer than six peer-befriending sessions.

Peer-befriender outcomes before and after befriending were summarised as mean differences pre and post and 95% CI for the 10 peer-befrienders who took part in the study.

All statistical analyses were completed using Stata, version 15. Qualitative interviews were transcribed verbatim and analysed using Framework Analysis.[26] Further details are provided elsewhere.[12]

SUPERB involved active patient, carer and public involvement (PCPI). While developing the proposal for this study, six people with aphasia reviewed and influenced our plans. Prior to recruitment, SUPERB had a six-month development phase, where six consultants with aphasia experienced in peer-befriending advised on: criteria for a peer-befriender, outcome measures, design of information sheets and consent forms, peer-befriending training manual and handbook and content of qualitative interviews. Lastly, during the course of the trial, a user group of four people with aphasia and one significant other advised on management issues, the implications of the findings and dissemination to the stroke community.

Results

Figure 1 (CONSORT diagram) shows participants journey through the study, including numbers identified, screened and randomised. The most common reasons for not fully screening those identified were living out of area, other mental health/cognition problems and comorbidities. The main reasons for ineligibility of those screened were declining consent and high emotional distress. For peer-befriender flow in the study, see Supplemental Material, Figure 1. Of 12 eligible peer-befrienders, 2 withdrew consent for personal reasons; 10 completed all peer-befriending and follow-up assessments.

Table 1 shows the baseline characteristics of the participants with aphasia. There were no missing baseline data at the question or scale level. Ethnicity and education level may be imbalanced between arms (more participants in Usual were white and with a university degree). A quarter of the sample had very severe/severe, and two-thirds mild aphasia. Almost half the participants had moderate or severe cognitive impairment (Cognitive-Linguistic Quick Test).[27]

Fourty-eight participants had significant others who also consented. The majority were female ($n=33$), white ($n=32$) and spouses/partners ($n=17$) or children ($n=15$) of the participant. Peer-befrienders were predominately female ($n=8$), white ($n=6$) and had suffered an ischaemic stroke ($n=6$) in the left hemisphere ($n=7$).

Demographic information capturing work, living and marital status was collected at all timepoints for participant groups to document change and appeared stable throughout the study (Supplemental Material Tables I and II).

Adherence to the intervention was high, with 24 (92%) attending at least two sessions and 21 (81%) attending all six. Sessions 7 and 8 were optional and had low uptake. Only three sessions were cancelled; 98% of sessions happened either as planned ($n=116$) or rescheduled ($n=27$).

Table 2 details the feasibility results. The proportion of those identified as potential participants that were found to be eligible was somewhat low at 10%; however, 84% of the individuals that were screened were eligible, with 83% of those eligible consenting to take part. The rate of consent was 3.4 participants per month and once consented there was a low proportion of withdrawals (7%).

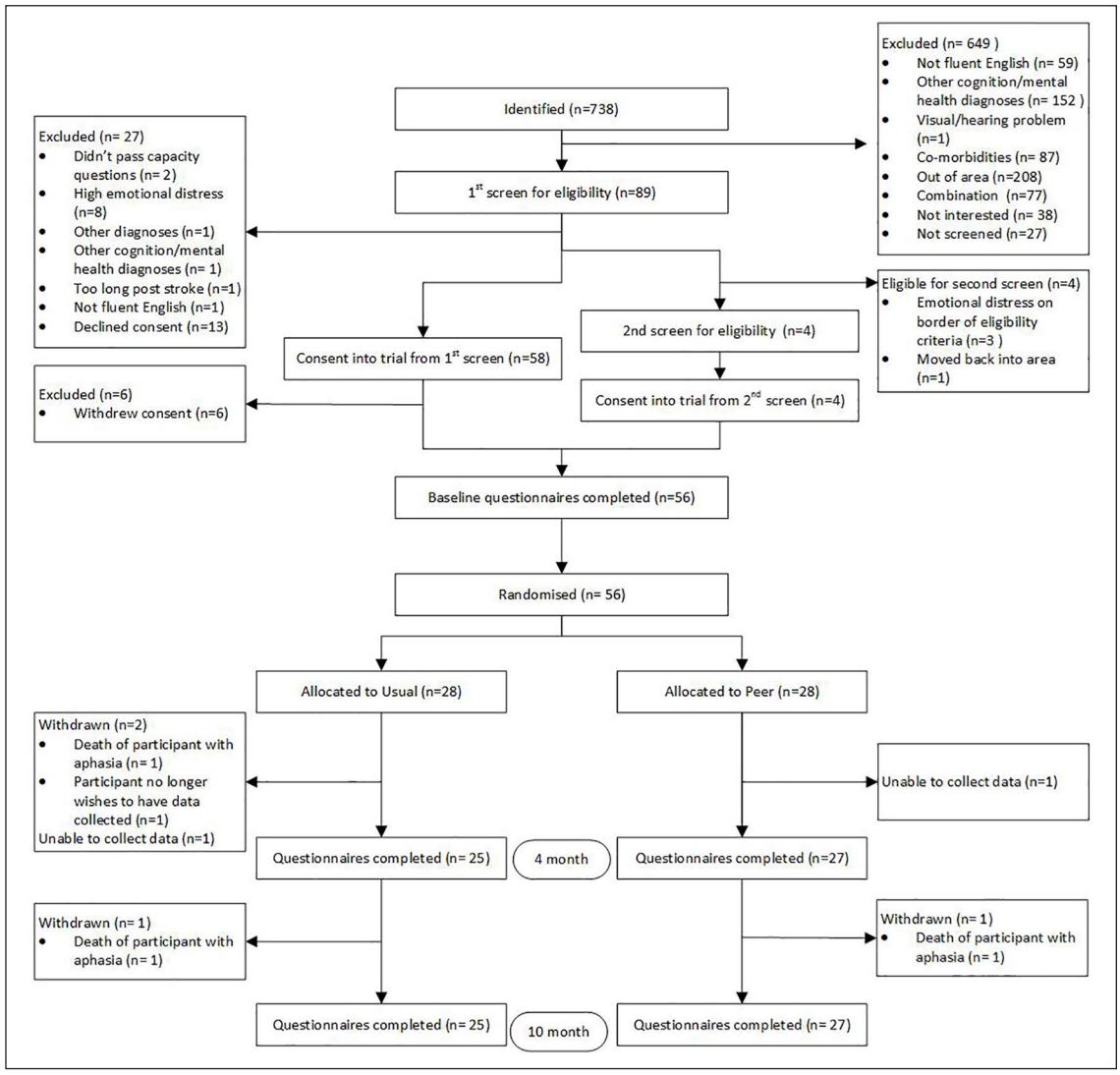

Figure 1. Participant CONSORT diagram.

Although all 28 in Peer consented to data collection, at the second stage of consent, two did not consent to the intervention.

In terms of acceptability of study procedures and outcome measure, as well as good retention of participants and low missing data, acceptability was also evidenced by data being collected within ±14 days of due date for 80% of participants at 4-months and 79% at 10-months; and 65% of significant others at both timepoints. Three instances of assessor unblinding occurred, all post-assessment; where applicable the assessor was changed for next assessment timepoint. Nine adverse events were recorded for participants; six were unrelated to the study, three related to outcome assessments: two participants got upset during an assessment; one significant other worried that some questions may upset the participant. One significant other got upset during one assessment. Three peer-befrienders scored >2 on the GHQ-12 after befriending, but did

Table 1. Participant baseline characteristics.

		Usual *N* = 28	Peer *N* = 28	Overall *N* = 56
		N (%)		
Age, mean (SD)		69.7 (13.4)	70.5 (13.7)	70.1 (13.4)
Gender	Female	14 (50.0)	13 (46.4)	27 (48.2)
Recruited from	Community	13 (46.4)	19 (67.9)	32 (57.1)
	Hospital	15 (53.6)	9 (32.1)	24 (42.9)
Ethnicity	Asian	1 (3.6)	1 (3.6)	2 (3.6)
	Black	3 (10.7)	11 (39.3)	14 (25.0)
	White	23 (82.1)	15 (53.6)	38 (67.9)
	Mixed	1 (3.6)	1 (3.6)	2 (3.6)
Work prior to stroke	Full-time	4 (14.3)	5 (17.9)	9 (16.1)
	Part-time	2 (7.1)	1 (3.6)	3 (5.4)
	Retired	20 (71.4)	19 (67.9)	39 (69.6)
	Looking after home	0 (0.0)	1 (3.6)	1 (1.8)
	Unemployed	2 (7.1)	2 (7.1)	4 (7.1)
Education	Did not finish school	9 (32.1)	9 (32.1)	18 (32.1)
	Finished school	8 (28.6)	9 (32.1)	17 (30.4)
	Further education qualification	4 (14.3)	5 (17.9)	9 (16.1)
	University degree	7 (25.0)	5 (17.9)	12 (21.4)
Stroke type	Ischaemic	23 (82.1)	23 (82.1)	46 (82.1)
	Haemorrhagic	5 (17.9)	2 (7.1)	7 (12.5)
	Both	0 (0.0)	3 (10.7)	3 (5.4)
Stroke class	Total anterior circulation	4 (14.3)	5 (17.9)	9 (16.1)
	Partial anterior circulation	21 (75.0)	21 (75.0)	42 (75.0)
	Posterior circulation	1 (3.6)	2 (7.1)	3 (5.4)
	Lacunar	2 (7.1)	0 (0.0)	2 (3.6)
Stroke hemisphere	Left	22 (78.6)	27 (96.4)	49 (87.5)
	Right	6 (21.4)	1 (3.6)	7 (12.5)
Time post stroke, days, *median* (IQR)		37 (8.5 – 83.5)	48 (21.5 – 86.5)	39.5 (15 – 86.5)
Aphasia quotient (Western Aphasia Battery-R)		70.3 (29.0)	73.1 (24.2)	71.7 (26.5)
Aphasia severity	Very severe/severe	7 (25.0)	7 (25.0)	14 (25.0)
	Moderate	2 (7.1)	3 (10.7)	5 (8.9)
	Mild	19 (67.9)	18 (64.3)	37 (66.1)
Cognition (Cognitive Linguistic Quick Test)	Severe	3 (10.7)	7 (25.0)	10 (17.9)
	Moderate	10 (35.7)	7 (25.0)	17 (30.4)
	Mild	7 (25.0)	9 (32.1)	16 (28.6)
	Normal limits	8 (28.6)	5 (17.9)	13 (23.2)

not self-report high distress and were positive about the intervention. There were no adverse events related to the intervention.

Acceptability was also probed within qualitative interviews. In terms of consent, there was no indication that participants regretted consenting or felt uninformed. A strong theme from participants with aphasia and significant others was a desire to contribute to research, both for their personal benefit and that of others; that they should 'do their bit'

Table 2. Feasibility outcomes.

	Proportion (%)/ rate [CI]	Numbers
Proportion eligible of those identified	10.2 [8.1, 12.6]	75/738
Proportion eligible of those screened	84.3 [75.0, 91.1]	75/89
At first screen	79.8 [70.0, 87.6]	71/89
At second screen	4.50 [1.2, 11.1]	4/89
Rate of eligible/month	4.2 [3.3, 5.2]	75
Proportion who consent of those eligible	82.7 [72.2, 90.4]	62/75
Rate of consent/month	3.4 [2.6, 4.4]	62
Rate of recruitment (randomisations)/month	3.1 [2.4, 4.0]	56
Proportion of withdrawals	16.1 [8.0, 27.7]	10/62
Before randomisation	9.7 [3.6, 19.9]	6/62
After randomisation		
Usual	10.7 [2.3, 28.2]	3/28
Peer	3.6 [0.1, 18.3]	1/28
Second stage consent in Peer	0	0/28
Second stage consent in Peer from intervention	7.1 [0.9, 23.5]	2/28
Overall (of those randomised)	7.1 [2.0, 17.2]	4/56
Overall (of those consented)	6.5 [1.8, 15.7]	4/62

or 'give something back.' Peer befrienders spoke of wanting to use their own experiences to help others. Recollection of assessments was variable. Participants appreciated researchers providing clarifications and breaks as needed. Overall, measures were considered appropriate and the time taken for completion acceptable. Participants perceived the logistics of the study, for example, arranging appointments, as straightforward. Peer-befrienders also found the study processes acceptable and considered the regular supervision and availability of one-to-one support indispensable. The high attendance of supervision confirmed this: the median (IQR) number of group sessions attended was 14 (8.0–18.0) out of 25, and 7.5 (7.0–8.0) individual sessions (total 77).

Table 3 shows the participant outcome data over trial timepoints. Table 4 details estimates of the comparison between Peer and Usual. The difference (CI) between groups at 10-months on the GHQ-12 was 1.23 points on average lower/better in Peer (0.17, −2.63). The categorical GHQ-12 indicated an 88% decrease in the odds of caseness (0.01, 1.01). The Community Integration Questionnaire favoured Usual, though the CI only just excluded a difference of zero. The friendship and communication participation measures showed a small benefit of the intervention, as did the depression and wellbeing measures but only at four-months; these comparisons should be interpreted cautiously as a difference of zero cannot be ruled out. Communication confidence showed no difference between groups. The differences between groups in the per-protocol population were similar (Supplemental Material, Table III).

Supplemental Figure 2 presents standardised estimated differences (numbers in Table IV, Supplemental Material). The largest effect at 10-months was for GHQ-12, with a moderate effect size, however, the CI is wide. Most other effect sizes at both 4- and 10-months were small.

The 4-month GHQ-12 scores ICC in the intervention arm was negligible (<0.0001) and at 10-months was 0.14 (CI 0.004, 0.86).

Significant other and peer-befriender outcomes are detailed in Supplemental Material Tables V and VI. Significant other outcomes were similar between groups. The largest effect size, which was still small, was for wellbeing at 4-months (0.26, CI −0.22, 0.73). There were no differences in outcomes for peer-befrienders.

Table 3. Participant outcomes across timepoints.

Scale [possible range]		Baseline			4 months			10 months		
		Mean (SD)								
		Usual $N=28$	Peer $N=28$	Overall $N=56$	Usual $N=25$	Peer $N=27$	Overall $N=52$	Usual $N=25$	Peer $N=27$	Overall $N=52$
General Health Questionnaire-12 (GHQ-12) [0–12]		4.3 (3.7)	3.5 (3.5)	3.9 (3.6)	3.2 (3.7)	2.0 (2.8)	2.6 (3.3)	2.7 (3.4)	1.2 (2.5)	1.9 (3.0)
	Median (IQR)	3.5 (1, 8)	3 (0, 5.5)	3 (0, 12)	2 (0, 4)	1 (0, 12)	1.5 (0, 3)	1 (0, 4)	0 (0, 1)	0 (0, 2.5)
GHQ-12 category *N (%)*	*0–2*	12 (42.9)	13 (46.4)	25 (44.6)	15 (60.0)	19 (70.4)	34 (65.4)	15 (60.0)	24 (88.9)	39 (75.0)
	⩾3	16 (57.1)	15 (53.6)	31 (55.4)	10 (40.0)	8 (29.6)	18 (34.6)	10 (40.0)	3 (11.1)	13 (25.0)
Depression intensity scale circles [0–5]		1.4 (1.2)	1.2 (1.5)	1.3 (1.3)	1.2 (1.4)	1.3 (1.4)	1.2 (1.4)	1.4 (1.2)	1.1 (1.3)	1.2 (1.3)
Short Warwick Edinburgh mental well-being scale [0–35]		24.7 (4.4)	25.5 (6.0)	25.1 (5.2)	24.5 (5.4)	26.2 (5.1)	25.4 (5.3)	25.6 (4.4)	25.9 (5.8)	25.7 (5.1)
Communication participation item bank [0–30]		13.0 (8.1)	15.0 (6.7)	14.0 (7.4)	15.6 (7.2)	17.9 (6.8)	16.8 (7.1)	14.4 (8.6)	17.3 (7.6)	15.9 (8.1)
Community integration questionnaire [0–29]		19.0 (6.5)	19.7 (5.7)	19.3 (6.1)	20.7 (5.4)	19.5 (5.8)	20.1 (5.6)	20.6 (5.9)	19.1 (5.3)	19.8 (5.6)
Friendship scale [0–30]		7.4 (5.9)	6.8 (5.5)	7.1 (5.7)	8.3 (6.1)	6.2 (5.0)	7.2 (5.6)	8.2 (6.1)	6.6 (5.7)	7.4 (5.9)
Communication confidence rating scale for Aphasia [0–40]		26.9 (6.9)	28.9 (6.6)	27.9 (6.8)	28.4 (7.6)	29.7 (7.2)	29.1 (7.3)	27.8 (7.2)	29.2 (7.4)	28.5 (7.3)

Table 4. Estimated differences between peer and usual arms.

	4 months		10 months	
	Estimate	CI	Estimate	CI
General Health Questionnaire-12 (GHQ-12)	−0.68	[−2.08, 0.73]	−1.23	[−2.63, 0.17]
GHQ-12 categorical (odds ratio)	0.73	[0.14, 3.91]	0.12	[0.01, 1.01]
Depression Intensity Scale Circles	0.19	[−0.40, 0.78]	−0.18	[−0.77, 0.42]
Friendship scale	−1.18	[−3.56, 1.20]	−0.65	[−3.03, 1.73]
Communication Participation Item Bank	1.39	[−2.14, 4.93]	2.27	[−1.26, 5.80]
Community Integration Questionnaire	−1.84	[−3.50, −0.17]	−1.63	[−3.30, −0.04]
Short Warwick Edinburgh Mental Well-Being Scale	0.93	[−1.50, 3.36]	−0.62	[−3.05, 1.82]
Communication Confidence Rating Scale for Aphasia	−0.20	[−2.83, 2.43]	−0.19	[−2.84, 2.45]

Estimates represent point differences on the scales between Peer and Usual arms after adjusting for baseline scores. A lower score shows a clinical improvement on the GHQ-12, Depression Intensity Scale Circles and Friendship scale. A higher score shows a clinical improvement on the Communication Participation Item Bank, Community Integration Questionnaire, Short Warwick Edinburgh Mental Well-Being Scale and Communication Confidence Rating Scale for Aphasia.

In terms of safety data, the mean GHQ-12 score for befrienders went up from 0.8 before to 2.0 after befriending (mean difference 1.2, CI −0.22, 2.62). This may be indicative of an increase in befriender distress, although it is still below the cut-off of three for high distress. There were few serious adverse events ($n = 10$) reported for the participants (six in Usual, four in Peer), all considered unrelated to the study. No serious adverse events were reported for significant others or peer-befrienders.

Discussion

We explored the feasibility of a definitive RCT of peer-befriending for people with aphasia post-stroke and low levels of distress, recruited at a time of increased need, when active care is withdrawn. Our sample had a good socioeconomic and ethnic mix and seemed representative of the population it was drawn from. It was very similar in average age and proportion of male, white and manual workers to the South London Stroke Register population.[28] Overall, it was feasible to recruit participants (people with aphasia, significant others, peer-befrienders) and retain them in the study, participants were able to complete all outcome measures, adherence to the intervention was high and study procedures and outcome measures were acceptable.

High adherence to the intervention and the small number of cancelled sessions provide evidence of intervention acceptability, as does the lack of attrition inflation despite the two-stage consent process. Intervention acceptability is explored further in a separate qualitative report. Informed by extensive user involvement, study procedures and outcome measures were acceptable to participants, as evidenced by qualitative data, low attrition and high completion rates. The discrepancy between overall and post-consent attrition stems mostly from the time interval between first approach/verbal consent to the study, which for most participants happened while they were still in hospital and randomisation/actual involvement in the study, when people were in the community.

A lot of work went into keeping participants engaged with the study, with quarterly newsletters, seasonal cards and text/phone calls between assessment points, one week and one day before assessment sessions. Nevertheless, ~20% of assessment sessions for participants and ~35% for significant others happened outside the ±14 days window. Many of these would probably not have happened if it were not for the perseverance and rapport of the trial manager with study participants, which has resource implications for a larger/multicentre trial. The excellent completion rates on outcome measures, despite 25% of participants having severe aphasia, were ensured by having assessors experienced in communicating with people with aphasia, training them on the outcome measures

used, using assessment packs with scripted instructions and modifying the presentation of measures to make them more aphasia-friendly.[12]

With the exception of proportion eligible of those identified, the feasibility parameters were positive. This should not mask the challenges of recruitment. In a systematic review of the efficiency of recruitment to stroke trials (512 RCTs, $n=28{,}804$), a third of those screened consented (median 34%, IQR 14–61), 1.5 participants (IQR 0.71–3.22) per site per month were recruited and 6% (IQR 0–13) dropped out. A higher proportion of those screened in the community (48%) and ⩾6 months post-stroke (47%) were recruited compared to those screened in hospital (27%) and ⩽1 month of stroke (23%).[29] To meet our targets, we provided training to recruiting staff in sites not just on our study's criteria but also on consenting processes with people with aphasia, which was positively received. We also contacted sites monthly to monitor targets. These processes should be taken forward in a definitive trial. Moreover, we extended our recruitment period from 12 to 18 months and the recruitment sites from hospitals to community services and GP practices. Such approaches have also been highlighted in other aphasia trials.[30,31]

Though the outcome data are only indicative in this feasibility study, they are encouraging particularly for the primary outcome, with lower levels of distress for those receiving peer-befriending. At 10-months 11% had high distress in Peer versus 40% in Usual. Moreover, the GHQ-12 was more discriminatory in the longer term. Whether this is a true effect needs to be determined in a definitive trial. Nevertheless, it speaks for the intended benefits of peer-befriending: to help people with low/sub-threshold distress, through emotional and social support, build their own resources to manage their condition and thus reduce or prevent depressive symptoms.[10]

A feature of peer-befriending is that the intervention provider is not a health professional or healthy volunteer, but a service user, here a person with aphasia. This creates opportunities but also additional demands. There is the unique opportunity of benefit not only for the person receiving but also the person delivering the intervention. Given the small number of befrienders in our trial, no change was detected in outcome measures. Their experiences were explored in qualitative interviews, where a main theme was that befrienders found involvement valuable and rewarding, it enabled them to feel they were making a difference and to reconnect with aspects of their pre-stroke identity. They also described a number of challenges and relied on supervision to handle these.[32] Despite regular support, an increase in GHQ-12 scores occurred. Though this may be a chance finding, it points to the need for regular supervision/support in a future trial and safety checks to ensure befriender wellbeing.

Strengths of the study included involvement of a Clinical Trials Unit and rigorous conduct to the standard of a definitive trial. We recruited and retained a substantial proportion of people with severe aphasia, which is uncommon in aphasia psychological interventions. Lastly, we offered a system of support that enabled peer-befrienders to successfully deliver the intervention.

In terms of limitations, a low proportion of those identified were eligible. In a future trial, having multiple sites and training more befrienders across different locations will prevent losing participants for living out of area. We used a usual-care control arm. Findings would be augmented by further studies comparing peer-befriending with alternative psychological interventions. Restrictions created by COVID-19 might suggest an online peer-befriending compared to face-to-face might be instructive.

We have demonstrated it was feasible to recruit participants with aphasia, significant others and peer-befrienders and retain them in the study; adherence to the intervention was good; and study procedures and outcome measures were acceptable to participants. All this was ensured by extensive PCPI before and during the trial; employing researchers with expertise in communicating with people with aphasia; and processes highlighted above to maximise engagement of sites, recruiters and participants in the study. Important estimates of attrition and ICC were calculated for a sample size calculation in a definitive study. There was preliminary evidence of benefit of peer-befriending, particularly for mood in the longer term. Peer-befriending is a promising intervention to reduce/prevent depression in the long-term post-stroke

and worth exploring in a definitive trial for people with aphasia and low/sub-threshold levels of distress.

Clinical messages

- It is feasible to deliver a peer-befriending intervention for people with aphasia at a time of increased need - when they are discharged from hospital and active care is withdrawn
- Peer-befrienders need training and ongoing supervision and support to effectively deliver the intervention

Acknowledgements

We thank the recruitment sites and the participants in the study. We also thank Katie Monnelly and Dr Abi Roper for their contribution in data collection. KG and KJ's contributions represent independent research part funded by the NIHR Biomedical Research Centre (South London and Maudsley NHS Foundation Trust and King's College London) and the NIHR Applied Research Collaboration South London (King's College Hospital NHS Foundation Trust). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, the Department of Health and Social Care or The Stroke Association.

Author contributions

KH designed the study with contributions from SN, JM, ST, AS, CF, SM and KG; all are grant holders and KH is principal investigator. KJ and KG analysed the quantitative data; SN and BM the qualitative data. KJ and KH wrote the paper and NB contributed. All authors contributed to the interpretation of the data, commented critically on the manuscript and read and approved the final version of the manuscript.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship and/or publication of this article: SUPERB was funded by The Stroke Association, Psychological Consequences of Stroke – Priority Programme Award [PPA2015-03].

ORCID iD

Katerina Hilari https://orcid.org/0000-0003-2091-4849

Supplemental material

Supplemental material for this article is available online.

References

1. Flowers HL, Skoretz SA, Silver FL, et al. Poststroke Aphasia frequency, recovery, and outcomes: a systematic review and meta-analysis. *Arch Phys Med Rehabil* 2016; 97: 2188–2201.e8.
2. Kauhanen ML, Korpelainen JT, Hiltunen P, et al. Aphasia, depression, and non-verbal cognitive impairment in ischaemic stroke. *Cerebrovasc Dis* 2000; 10: 455–461.
3. Ayerbe L, Ayis S, Wolfe CD, et al. Natural history, predictors and outcomes of depression after stroke: systematic review and meta-analysis. *Br J Psychiatry* 2013; 202: 14–21.
4. Pohjasvaara T, Vataja R, Leppavuori A, et al. Depression is an independent predictor of poor long-term functional outcome post-stroke. *Eur J Neurol* 2001; 8: 315–319.
5. Ghose SS, Williams LS and Swindle RW. Depression and other mental health diagnoses after stroke increase inpatient and outpatient medical utilization three years post-stroke. *Med Care* 2005; 43: 1259–1264.
6. Baker C, Worrall L, Rose M, et al. Stroke health professionals' management of depression after post-stroke aphasia: a qualitative study. *Disabil Rehabil*. Epub ahead of print 10 June 2019. DOI: 10.1080/09638288.2019.1621394.
7. Allida S, Cox KL, Hsieh CF, et al. Pharmacological, psychological, and noninvasive brain stimulation interventions for treating depression after stroke. *Stroke* 2020; 51: e259–e260.
8. Kessler D, Egan M and Kubina LA. Peer support for stroke survivors: a case study. *BMC Health Serv Res* 2014; 14: 256–256.
9. Mead S, Hilton D and Curtis L. Peer support: a theoretical perspective. *Psychiatr Rehabil J* 2001; 25: 134–141.
10. Mead N, Lester H, Chew-Graham C, et al. Effects of befriending on depressive symptoms and distress: systematic review and meta-analysis. *Br J Psychiatry* 2010; 196: 96–101.
11. Haun J, Rittman M and Sberna M. The continuum of connectedness and social isolation during post stroke recovery. *J Aging Stud* 2008; 22: 54–64.
12. Hilari K, Behn N, Marshall J, et al. Adjustment with aphasia after stroke: study protocol for a pilot feasibility randomised controlled trial for SUpporting wellbeing through PEeR Befriending (SUPERB). *Pilot Feasibility Stud* 2019; 5: 1–16.
13. Turner-Stokes L, Kalmus M, Hirani D, et al. The Depression Intensity Scale Circles (DISCs): a first evaluation of a simple

assessment tool for depression in the context of brain injury. *J Neurol Neurosurg Psychiatry* 2005; 76: 1273–1278.
14. Kertesz A. *Western aphasia battery- revised*. Hoboken, NJ: Pearson, 2006.
15. Forster A, Dickerson J, Young J, et al. A cluster randomised controlled trial and economic evaluation of a structured training programme for caregivers of inpatients after stroke: the TRACS trial. *Health Technol Assess (Winchester, England)* 2013; 17: 1–216.
16. Goldberg DP and Williams P. *A user's guide to the general health questionnaire (GHQ)*. Oxford: NFER-Nelson, 1988.
17. Ng Fat L, Scholes S, Boniface S, et al. Evaluating and establishing national norms for mental wellbeing using the short Warwick–Edinburgh Mental Well-being Scale (SWEMWBS): findings from the Health Survey for England. *Qual Life Res* 2016; 26: 1129–1144.
18. Baylor C, Yorkston K, Eadie T, et al. The Communicative Participation Item Bank (CPIB): item bank calibration and development of a disorder-generic short form. *J Speech Lang Hear Res* 2013; 56: 1190–1208.
19. Dalemans RJ, de Witte LP, Beurskens AJ, et al. Psychometric properties of the community integration questionnaire adjusted for people with aphasia. *Arch Phys Med Rehabil* 2010; 91: 395–399.
20. Cherney LR, Babbitt EM, Semik P, et al. Psychometric properties of the communication Confidence Rating Scale for Aphasia (CCRSA): phase 1. *Top Stroke Rehabil* 2011; 18: 352–360.
21. Hawthorne G. Measuring social isolation in older adults: development and initial validation of the friendship scale. *Soc Indic Res* 2006; 77: 521–548.
22. Tennant R, Hiller L, Fishwick R, et al. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation. *Health Qual Life Outcomes* 2007; 5: 63.
23. Bakas T and Champion V. Development and psychometric testing of the Bakas Caregiving Outcomes Scale. *Nurs Res (New York)* 1999; 48: 250–259.
24. Schwarzer R and Jerusalem M. Generalized self-efficacy scale. In: Weinman J, Wright S and Johnston M (eds) *Measures in health psychology: a user's portfolio. Causal and control beliefs*. Windsor, UK: NFER-Nelson, 1992, pp.35–37.
25. Sim J and Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012; 65: 301–308.
26. Ritchie J and Spencer L. Qualitative data analysis for applied policy research. In: Bryman A and Burgess R (eds). *Analysing qualitative data*. London: Routledge, 1994.
27. Helm-Estabrooks N. *Cognitive linguistic quick test (CLQT)*. Hoboken, NJ: Pearson, 2001.
28. Wang Y, Rudd AG and Wolfe CD. Age and ethnic disparities in incidence of stroke over time: the South London Stroke Register. *Stroke* 2013; 44: 3298–3304.
29. McGill K, Sackley CM, Godwin J, et al. A systematic review of the efficiency of recruitment to stroke rehabilitation randomised controlled trials. *Trials* 2020; 21: 1–2.
30. Horton S, Clark A, Barton G, et al. Methodological issues in the design and evaluation of supported communication for aphasia training: a cluster-controlled feasibility study. *BMJ Open* 2016; 6: e011207.
31. Palmer R, Enderby P, Cooper C, et al. Computer therapy compared with usual care for people with long-standing aphasia poststroke: a pilot randomized controlled trial. *Stroke* 2012; 43: 1904–1911.
32. Northcott S, Behn N, Monnelly K, et al. "For them and for me": a qualitative exploration of peer befrienders' experiences supporting people with aphasia in the SUPERB feasibility trial. *Disabil Rehabil*. Under submission.